access routes were transfemoral (n=164), transapical (n=54), axillary (n=5), or transaortic (n=4). A CoreValve prosthesis was implanted in 174 patients, and a Sapien prosthesis in 53 patients. Clinical and echocardiographic investigation was performed at 6 months, one and two years.
Results: Survival was 88.5% at 30 days, 75.9% at six months, 74.5% at 1 year, and and 64.4% at 2 years. Patients improved significantly in NYHA class after 6 months (from 3.2±0.5 to 1.7±0.7, p<0.001) and up to two years (1.9±0.7). Cumulate incidences of myocardial infarction, stroke, life-threatening or major bleeding were 2.7%, 6.2%, and 16.2% at two years. The postprocedural mean transprosthetic gradient was 12±4 mmHg for all valves and did not change up to 2 years, the effective orifice area was 1.5±0.4 cm2 without any change over 2 years of FU. Moderate or severe prosthetic regurgitation was present in 8% of patients at two years. In 6% of patients, the paravalvular or valvular regurgitation grade increased significantly over time.
Conclusion: With excellent functional recovery of the patients, good systolic valve function, and overall low morbidity at two years, we conclude TAVI can be considered the treatment of choice for aortic valve stenosis in the elderly patient with an increased risk for surgery with heart-lung-machine.

TCT-787

Australian and New Zealand Source Registry: Edwards Sapien Transcatheter Aortic Valve Replacement- 30 Day Outcomes

Darren Walters[1], Ajay Sinhal[8], David Barron[6], Sanjaveen Pasupati[5], Suku Thambar[4], Nigel Jepson[3], Gerald Yong[7], Allen James[4], Hugh Wolfenden[3], Adam El Gamel[5], Peter Brady[2], Paul Jansz[6], Ravi Bhindi[6], Robert Larbalestier[7], Andrew Clarke[1], Jamie Bennetts[8], Derek Chew[8]
[1]Cardiology, The Prince Charles Hospital, Chermside, Australia; [2]Royal North Shore Hospital, Sydney, Australia; [3]Prince of Wales Hospital, Sydney, Australia; [4]John Hunter Hospital, Newcastle, Australia; [5]Waikato Hospital, Hamilton, New Zealand; [6]St. Vincents Hospital, Sydney, Australia; [7]Royal Perth Hospital, Perth, Australia; [8]Flinders Medical Centre, Adelaide, Australia

Background: Transcatheter aortic valve replacement (TAVR) may be considered for those with severe aortic stenosis who are considered inoperable or at high risk for surgical replacement. We report the 30 day outcomes of the Edwards Sapien Source Registry in Australia and New Zealand
Methods: This study enrolled 133 subjects at eight centres since December 2008. Inclusion criteria included severe symptomatic aortic valve disease, symptomatic degenerative aortic stenosis (AVA ≤ 0.8cm2), logistic Euroscore > 20% or STS > 10%, agreement between surgeon and cardiologist that the patient not suitable for open surgery due to high risk.
Results: A total of 133 were enrolled with complete data for 99 patients consisting of 53 transfemoral (TF) and 46 transapical (TA) implants. The mean age 82.6 yr (TF) and 83.6 yr (TA), female 32.1% (TF) 56.5% (TA), logistic Euroscore 27.6% (TF) 30.7% (TF) with procedural success (successful implant without conversion to surgery or death) of 92.3% (TF) 87% (TA) (p=0.384). Thirty day outcomes were not significantly different between TF and TA implants. These included mortality of 3.8% (TF) 8.7% (TA) (p=0.38), Major Adverse Cardiac and Cerebrovascular Events 5.7% (TF) and 13.0% (TA) (p=0.205), pacemaker 2.2% (TF) 0% (TA) (p=0.283), and VARC major vascular complication of 6.5% (TF) 5.7% (TA) (p=0.859).
Conclusion: TAVR with the Edwards Sapien device is safe and effective therapy by TA or TF route. A high procedural success rate was achieved with an acceptable incidence of adverse events for a patient group at high risk for open surgery.

TCT-788

3- Months Results of the JenaValve Multicenter Study Evaluating a Second Generation Transcatheter Aortic Valve Implantation System

Hendrik Treede[1], Stephan Baldus[5], Hans-Reiner Figulla[2], Markus Ferrari[2], Ardawan Rastan[3], Andreas Marx[4], Kathrin Leadley[4], Friedrich-Wilhelm Mohr[3]
[1]Department of Cardiovascular Surgery, University Heart Center Hamburg, Hamburg, Germany; [2]University Hospital Jena, Jena, Germany; [3]Heart Center Leipzig, Leipzig, Germany; [4]JenaValve Technology, Munich, Germany; [5]University Heart Center Hamburg, Hamburg, Germany

Background: Trancatheter aortic valve implantation (TAVI) has emerged as an accepted treatment option for high risk patients with severe aortic stenosis. The study was designed to evaluate the safety and efficacy of transapical aortic valve implantation in high risk patients using a second generation TAVI device, the JenaValveTM aortic valve replacement system. It consists of a biological porcine valve mounted on a self-expanding Nitinol stent. Retrieval capability, feeler guided anatomically correct positioning, and clipping fixation on the diseased leaflets provide potential advantages compared to current TAVI systems.
Methods: This is a prospective, single arm study conducted at seven German sites including up to 70 patients. Enrollment started in November 2010 and will be completed in June 2011.The valve is implanted via apical approach without rapid pacing under fluoroscopic control. Primary endpoint is all cause mortality at 30 days. Secondary endpoints, procedural success, major adverse cerebrovascular and cardiac events, functional improvement and echocardiographic valve performance will be assessed at procedure, post-procedure, discharge, 30 day, 3, 6, and 12 months.
Results: Three months safety and effectiveness outcomes will be presented for high risk patients undergoing transapical aortic valve implantation. For primary and secondary categorical endpoints estimates of absolute frequencies relative to patients at risk and their 95% two-sided confidence interval will be calculated. Changes to baseline will be given for all variables recorded at different time points, and tests on pre-post difference will be performed with methods suited to scale this data.
Conclusion: Transapical aortic valve implantation has shown to be an excellent treatment option in high risk patients with symptomatic aortic stenosis. However, reports on clinical outcomes using second generation devices are still limited. The study results will provide important data about the safety and efficacy of this next generation device.

TCT-789

Clinical Profile and Outcome Correlates in Patients with Severe Aortic Stenosis at High Surgical Risk: Prospective Evaluation According to Treatment Assignment

Danny Dvir, Alexander Sagie, Eyal Porat, Abid Assali, Yaron Shapira, Hana Vaknin-Assa, Vachislav Bobovnikov, Gideon Shafir, Tamir Bental, Nurit Shor, Arnon Koren, Leonid Eidelman, Alexander Battler, Ran Kornowski
Rabin Medical Center, Petah-Tikva, Israel

Background: Transcatheter aortic-valve implantation (TAVI) is a therapeutic alternative to surgical aortic-valve replacement (SAVR) in high-risk patients with severe aortic stenosis (AS). Patients ineligible for both SAVR and TAVI are treated with medication, with or without balloon valvuloplasty (BV). There are very few data on the outcome of these patients according to the treatment assigned in the current TAVI era.
Methods: The study included 403 high-risk patients (55.8% female, age 81.4±7.1 years) with severe AS referred to a dedicated "TAVI clinic" with meticulous screening and multidisciplinary team evaluation. Technical and procedural success (VARC definitions) and outcome were assessed during median follow-up of 292 days (IQR 138-522).
Results: Of the 343 patients assigned treatment, 100 (29.2%) underwent TAVI (56 CoreValve, 44 Edwards-SAPIEN), 61 (17.8%) SAVR, and 27 (7.9%) BV; 155 patients (45.2%) were given medication only. The BV group had more comorbidities than the other groups, represented by a higher logistic EuroSCORE (30.2±21.6 vs. 22.9±14.3, p<0.001) and STS score (14.1±6.7 vs. 10.8±5.3, p<0.001). One-month mortality rate was higher in the BV group (18.5%) than in each of the other groups (TAVI 3%, SAVR 11.8%, medication 3.2%; p<0.001). At one-year, patients after TAVI and SAVR had lower mean valve gradients (8+4.6mmHg and 13+5.2, respectively) than the BV group (29.4±18.6) and the medication group (46.2±24.3) (p<0.001); rates of high functional class (NYHA I/II) were as follows: TAVI, 91%; SAVR, 79%; BV, 38%; medication, 16% (p<0.001). One-year mortality rate was dramatically lower in the TAVI group (8.5%) than in the other groups (SAVR 29.8%, BV 39.6%, medication 38.7%; p< 0.001). Multivariable adjustment analysis identified renal failure (GFR<60cc/min, HR: 4.5, p<0.001) and pulmonary pressure (1mmHg, HR: 1.02, p=0.002) as independent correlates for 1-year mortality in the total group; STS score (1%, HR: 1.1, p=0.001) in the AVR group and peripheral vascular disease and in the BV group (HR 6.9, p=0.015).
Conclusion: This prospective clinical evaluation suggests that among the treatment options for high-risk patients with severe AS, TAVI is associated with an excellent prognosis in carefully selected patients. Patients excluded from TAVI had worse outcomes, regardless of the elected mode of treatment, including SAVR.

TCT-790

Late Occurrence of Bradyarrhythmias After TAVI with the CoreValve® Aortic Bioprosthesis

Emmanuel Chorianopoulos, Ulrike Krumsdorf, Sven T Pleger, Hugo A Katus, Raffi Bekeredjian
Department of Cardiology, Angiology and Pulmology, Heidelberg University Hospital, Heidelberg, Germany

Background: Transcatheter aortic valve replacement (TAVI) has become an alternative therapy in patients with high surgical risk. Among the major drawbacks of this procedure is the potential need for postprocedural permanent pacemaker implantation (PPM) due to bradyarrhythmias.
Methods: We performed a retrospective single center analysis in 130 consecutive patients with successful transfemoral Corevalve implantation without preexisting PPM implants and analyzed postinterventional bradyarrhythmias.
Results: Postprocedural bradyarrhythmias occurred in 47 patients (36.2%) post-TAVI. PPM was performed in 46 patients. One patient died due to asystole. Compared to those without postinterventional bradyarrhythmias, these patients had longer preprocedural PR-intervals (P=0.012), broader QRS-complexes (P=0.001) and prolonged QTc-intervals (P=0.001). Moreover, patients with postinterventional bradyarrhythmias had more often preprocedural RBBB (P=0.0059) and a strong trend towards increased numbers of preprocedural AVB grade I (P=0.0637). No difference was observed with respect to annulus/prosthesis ratio (P = 0.377) or the use of a large prosthesis (P = 0.2320). The vast majority developed bradyarrhythmias directly after CoreValve implantation or within the first 48 hours (37 out of 47 patients). However, the remaining 10 patients developed significant bradyarrhythmia more than 72 hours after TAVI, when the provisional pacemaker had already been removed, and among them were 5 patients (3.8% of the whole cohort), who developed them very late after TAVI (240±129 h post TAVI), of which 1 died from asystole at day 5 post TAVI. The

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